“Transparency Guideline for the Relation between Corporate Activities and Medical Institutions”

- Introduction -

The Japan Pharmaceutical Manufacturers Association

(Mission of R&D based pharmaceutical companies — Contribution to people’s health)

The mission of R&D based pharmaceutical companies is to contribute to the realization of “patient-participation-type medicine” through continuous R&D activities and through the stable supply of new medicines for the advance of global medical care and people’s health. In order to accomplish this mission, by collaborating with research organizations such as universities and medical institutions, pharmaceutical companies conduct various activities such as basic medical and pharmaceutical research, clinical development, provision/collection of post-marketing information, safety-securing measures, relief from adverse drug reactions, etc. in order to contribute to the improvement of people’s health, through the supply of medicines and vaccines. The collaboration between pharmaceutical companies and research organizations such as universities and medical institutions are essential for such activities. In order to create innovative medicines, process based on the Pharmaceutical Affairs Law, such as basic research, nonclinical studies and clinical studies are essential. After investigation of efficacy and safety, regulatory review by the Pharmaceuticals and Medical Devices Agency and approval by the Minister of Health, Labor and Welfare are also necessary for the actual birth of a new medicine. As many as 9 to 17 years are necessary for developing one new medicine, and the success rate in development of a new medicine is extremely low. Furthermore, enormous research and development costs reaching several dozen - hundred billion yen are necessary to develop one new medicine, and also these costs are increasing year by year.

(Collaboration between pharmaceutical companies and medical institutions, etc. — Efforts towards creation of new medicines and safety-securing measures)

In recent years, medicines have made remarkable advances and have been helpful to save patients from various diseases in clinical practice. For example, some therapeutic medicines were created against the diseases which used to show a high death rate due to the absence of therapeutic method, some diseases requiring surgery have become curable only with drug therapy, and some medicines have shown remarkable efficacy against cancer or rheumatoid arthritis as compared with the conventional therapies. Such new medicines meeting patient’s needs and medical needs can neither be created by pharmaceutical companies alone
nor by academic research organizations such as universities and medical institutions alone. Collaboration between pharmaceutical companies and academic organizations only enables creation of such medicines. Collaboration between pharmaceutical companies and academic organizations (so-called “industry-academia collaboration”) includes joint research, commissioned research, and also support of academic research through donation, etc. Such industry-academia collaboration, which are also promoted in the Government’s Basic Program for Science and Technology, contribute to return the results of academic research back to the society resulting in the advancement of Japan’s medical services.

Although new medicines are approved and marketed under strict regulations, after the confirmation of safety and efficacy, new medicines are used in a large number of diverse patients when marketed and are administered under different circumstances from clinical studies. Therefore, pharmaceutical companies are obligated to further collect, analyze and assess safety and efficacy data of marketed medicines, by collaborating with medical institutions and healthcare professionals, and also to provide these information to healthcare professionals. The efficacy and safety of new medicines are further clarified through these activities, and further appropriate use is investigated, and then will be disseminated to medical institutions and healthcare professionals.

(Information provision/collection for proper use of medicines — Efforts to foster medicines)

It is said that “Medicines are chemical substances accompanied with information”. This is because the purpose of medicines are accomplished only when they are used properly based on information such as indications, dosage and administration, action mechanism and adverse drug reactions. Recently, medicines have become increasingly specialized, and it has become more necessary than before for to hold educational activities by specialist physicians for appropriate use. For this reason, with the cooperation of specialist physicians, pharmaceutical companies provide various opportunities such as academic lecture meetings and research conferences for healthcare professionals, in order to penetrate information on proper use of medicines, to enable information sharing of safe and effective use, and to enable exchange of information on the latest findings. Pharmaceutical companies enter into contracts with specialist physicians and researchers from various disease areas in order to obtain advices from their professional aspects, for their new medicines under development, or for their plans to provide post-marketing information. These activities are very important for marketed medicines to be used further safely and properly for the patients.
These industry-academia collaboration, which is essential for medical and pharmaceutical research, practical realization and penetration of proper use of medicines are conducted through contracts with medical institutions and healthcare professionals. These activities are often accompanied by monetary payments in return for their contribution. Therefore, in addition to full compliance with the laws and regulations including the Pharmaceutical Affairs Law, pharmaceutical companies have made efforts to make such activities transparent by establishing industry self-regulations based on high ethical standards, such as “JPMA Corporate Activity Charter”, “JPMA Compliance Program Guideline, “JPMA Code of Practice” and “Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry”. However, as such collaboration increase more and more, there may be cases where medical institutions or healthcare professionals become closely related with specific pharmaceutical companies or specific medicines, and it can not be denied that there could be concerns that such activities may have some influence on their judgments. In Japan’s pharmaceutical industry closely involved with life and health of people and patients, and as a life-related industry under the universal health insurance coverage system, such activities should be more transparent than in other industries. From this view point, the Japan Pharmaceutical Manufacturers Association has prepared this Guideline for the purpose of increasing the transparency of the member company’s activities so that Japan’s pharmaceutical industry gains further higher trust from the society.